

Remarks

In the Office Action, the Examiner set forth several grounds of rejection under 35 USC § 112. These matters are addressed separately herein.

Rejections under 35 USC § 112

Claims 1 - 6 and 10 - 15 were rejected under 35 USC § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to use the invention. According to the Examiner, the instant application does not disclose a specific biological role for IL-1 delta or its significance to a particular disease, disorder or physiological process. Applicant respectfully disagrees.

The present specification discloses the role of IL-1 delta in modulating the physiological process of inflammation, which physiological process is known to play a causative role in a number of disorders, including those taught in the instant application (see, for example, pages 43 and 44). The previously submitted evidence is not *de novo* evidence of the role of IL-1 delta in inflammation, but confirmation of Applicant's disclosure of the role of IL-1 delta in this physiological process.

Moreover, while Debets et al. may have referred to IL-1R6 as 'orphan' receptor in the IL-1 receptor family, they provided evidence of IL-1R6-mediated activation of NF- κ B upon stimulation with IL-1 epsilon-1 (see Figure 4), and further demonstrated that IL-1 delta specifically antagonizes the IL-1R6-mediated response to IL-1 epsilon (see Figure 5). Thus, while those of skill in the art may have classified IL-1R6 as an 'orphan' receptor prior to Debets et al. because it was not known to be activated any of the known members of the IL-1 family, demonstration by Debets et al. of the activation thereof by IL-1 epsilon confirmed its place in this receptor family, and, along with studies of expression of IL-1R6, IL-1 epsilon and IL-1 delta, its role in the inflammatory process.

Accordingly, Applicant has taught the role of IL-1 delta in modulating inflammation, which role was confirmed by other investigators. There is no reason to doubt the objective truth of the statements contained in applicants' specification; accordingly, applicants request that the rejection be withdrawn.

Claims 1 - 6 remain rejected under 35 USC § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to use the invention. According to the Examiner, the instant specification fails to describe the entire genus of proteins encompassed by the claims because the claims only require that the polypeptide share some degree of structural similarity to the isolated polypeptide. The Examiner further alleges that the instant

application fails to recite relevant identifying characteristics such that the skilled artisan would recognize Applicant was in possession of the invention. Applicant respectfully disagrees.

Applicant provided the primary structure (amino acid sequence) of the polypeptides in the claims. Moreover, Applicant identified these polypeptides as members of the IL-1 family. As shown in the Exhibits enclosed with the previous Response, correlation of functional characteristics of this family with structure was known in the art. Moreover, Applicant has amended the claims to recite peptides that are at least 95% identical to the polypeptide of SEQ ID NO:4. Applicant specifically reserves the right to pursue claims directed to use of polypeptides that are at least 80% identical to that of SEQ ID NO:4 in a continuing application.

Applicant respectfully submits that the specification demonstrates possession of not only the exact sequences disclosed but of variants thereof. Any requirement that Applicant limit the claims to specific embodiments does not adequately protect Applicant in view of the scope of the invention and the disclosure. Thus, to demand that Applicant limit the claimed invention to specific IL-1 delta polypeptides when it is well within the knowledge of those skilled in the art to use routine experimental techniques to make and test IL-1 delta DNA and polypeptides that are antagonists of inflammatory conditions is improper. Applicants request that the rejection be withdrawn.

Claim 1 was rejected under 35 USC § 112, second paragraph, as allegedly being indefinite. According to the Examiner, claim 1 is indefinite for reciting hybridization conditions parenthetically, which renders the conditions exemplary. Claim 1 has been amended to remove the parentheses from the hybridization conditions. Applicant respectfully asserts that this amendment does not change the scope of the claims, but merely makes them clearer to one of ordinary skill in the art. Accordingly applicant requests that this aspect of the rejection be withdrawn.

CONCLUSIONS

Claims 1 through 6 and 10 through 15 are now under consideration in the application and are believed to be in condition for allowance. Notification to this effect is respectfully requested.

Applicant hereby states that the substitute specification filed on June 6, 2003 contains no new matter. If any issues of concern remain in this application, the Examiner is invited to contact the undersigned at the direct dial number given below.

Respectfully submitted,



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